

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111  
 Serial Number: 09/955,623  
 Filing Date: September 19, 2001  
 Title: Plunger For Patient Infusion Device

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### Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

#### Listing of Claims:

1 (currently amended). A device for delivering fluid to a patient, comprising:

- a) an exit port assembly adapted to connect to a transcutaneous patient access tool;
- b) a reservoir including a side wall extending from a first end wall towards a second end wall and an outlet connected to the exit port assembly;
- c) at least one threaded lead screw received in the reservoir and extending towards the outlet of the reservoir generally parallel with the side wall and so that the lead screw is directly coupled to at least one of said first and second end walls;
- d) a plunger threadedly received on the lead screw such that rotating one of the lead screw and the plunger moves the plunger within the reservoir; and
- e) a dispenser operatively coupled to one of the lead screw and the plunger for rotating one of the lead screw and the plunger.

2 (original). A device according to Claim 1, wherein the dispenser rotates the lead screw.

3 (original). A device according to Claim 2, wherein the plunger is prevented from rotating with respect to the side wall of the reservoir.

4 (withdrawn). A device according to Claim 3, wherein the side wall of the reservoir and the plunger have a non-circular cross-section.

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5 (withdrawn). A device according to Claim 4, wherein the side wall of the reservoir and the plunger have an oval cross-section.

6 (withdrawn). A device according to Claim 3, wherein the side wall of the reservoir includes a channel extending parallel with the lead screw, and the plunger includes a protrusion slidingly received in the channel.

7 (original). A device according to Claim 1, wherein the plunger includes an insert threadedly received on the lead screw and wherein the threaded insert and the plunger are made from different materials.

8 (original). A device according to Claim 1, wherein the threaded lead screw is made from a plastic.

9 (withdrawn). A device according to Claim 1, wherein the device further comprises a fill port, and the reservoir also includes an inlet connected to the fill port.

10 (withdrawn). A device according to Claim 9, wherein the fill port includes a septum for sealingly receiving a needle.

11 (withdrawn). A device according to Claim 9, further comprising a plug biased to a first position opening the outlet of the reservoir and sealing the inlet of the reservoir, and movable to a second position sealing the outlet of the reservoir and opening the inlet of the reservoir.

12 (withdrawn). A device according to Claim 9, wherein the plunger comprises a first plunger threadedly received on the lead screw and a second plunger slidingly received on the lead screw.

13 (withdrawn). A device according to Claim 12, wherein the second plunger is positioned between the first plunger and the outlet of the reservoir.

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14 (withdrawn). A device according to Claim 12, wherein the inlet of the reservoir is positioned between the second plunger and the first plunger.

15 (currently amended). A device according to Claim 1, wherein the lead screw is rotated in a single direction so that the plunger is movable in a single direction on the lead screw.

16 (withdrawn). A device according to Claim 1, wherein the lead screw includes a non-threaded portion adjacent the outlet of the reservoir.

17 (withdrawn). A device according to Claim 1, wherein the dispenser comprises:

a clock spring operatively connected to the lead screw for causing the lead screw to rotate;

a gear radially extending from the lead screw; and

a ratchet for movement between engaging the gear for preventing the clock spring from rotating the lead screw, and disengaging the gear for allowing the clock spring to rotate the lead screw.

18 (original). A device according to Claim 1, wherein the dispenser comprises a motor.

19 (withdrawn). A device according to Claim 1, further comprising a sensor for determining the position of the plunger within the reservoir.

20 (withdrawn). A device according to Claim 19, wherein the lead screw includes a linear encoder and the sensor comprises a magnetic sensor mounted on the plunger.

21 (withdrawn). A device according to Claim 1, further comprising a release mechanism for allowing the plunger to be moved within the reservoir during filling of the reservoir.

22 (withdrawn). A device according to Claim 1, further comprising a removable plug closing the exit port assembly.

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23 (original). A device according to Claim 1, further comprising a transcutaneous patient access tool connected to the exit port assembly.

24 (withdrawn). A device for delivering fluid to a patient, comprising:

- a) an exit port assembly adapted to connect to a transcutaneous patient access tool;
- b) a reservoir including a side wall extending towards an outlet connected to the exit port assembly;
- c) a plunger slidably received within the side wall of the reservoir;
- d) a shaft extending from the plunger, the shaft relatively incompressible along an axis of the shaft and bendable transverse to the axis; and
- e) a dispenser operatively coupled to the shaft for causing movement of the shaft along the axis of the shaft.

25 (withdrawn). A device for delivering fluid to a patient, comprising:

- a) an exit port assembly adapted to connect to a transcutaneous patient access tool;
- b) a reservoir including an outlet connected to the exit port assembly;
- c) a plunger movably received in the reservoir for forcing fluid through the outlet upon moving within the reservoir;
- d) a dispenser for moving the plunger within the reservoir;
- e) a local processor connected to the dispenser and programmed to cause the dispenser to move the plunger based on flow instructions;

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f) a wireless receiver connected to the local processor for receiving flow instructions from a separate, remote control device and delivering the flow instructions to the local processor; and

g) a housing containing the exit port assembly, the reservoir, the dispenser, the local processor, and the wireless receiver;

wherein the housing is free of user input components for providing flow instructions to the local processor.

26 (withdrawn). A device according to Claim 25, further comprising a threaded lead screw received in the reservoir, and wherein the plunger is threadedly received on the lead screw such that rotating one of the lead screw and the plunger moves the plunger within the reservoir, and wherein the dispenser is adapted to rotate one of the lead screw and the plunger.

27 (withdrawn). A device according to Claim 26, wherein the dispenser comprises a motor for rotating one of the lead screw and the plunger.

28 (withdrawn). A device according to Claim 26, wherein the plunger includes an insert threadedly received on the lead screw and wherein the threaded insert and the plunger are made from different materials.

29 (withdrawn). A device according to Claim 26, wherein the threaded lead screw is made from a plastic.

30 (withdrawn). A device according to Claim 26, wherein the plunger is prevented from rotating with respect to the reservoir.

31 (withdrawn). A device according to Claim 26, wherein the dispenser rotates the lead screw to move the plunger.

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32 (withdrawn). A device according to Claim 26, wherein the device further comprises a fill port, and the reservoir also includes an inlet connected to the fill port.

33 (withdrawn). A device according to Claim 32, wherein the fill port includes a septum for sealingly receiving a needle.

34 (withdrawn). A device according to Claim 32, further comprising a plug biased to a first position opening the outlet of the reservoir and sealing the inlet of the reservoir, and movable to a second position sealing the outlet of the reservoir and opening the inlet of the reservoir.

35 (withdrawn). A device according to Claim 32, wherein the plunger comprises a first plunger threadedly received on the lead screw and a second plunger slidingly received on the lead screw.

36 (withdrawn). A device according to Claim 35, wherein the second plunger is positioned between the first plunger and the outlet of the reservoir.

37 (withdrawn). A device according to Claim 35, wherein the inlet of the reservoir is positioned between the second plunger and the first plunger.

38 (withdrawn). A device according to Claim 26, wherein the plunger is movable in a single direction on the lead screw.

39 (withdrawn). A device according to Claim 26, wherein the lead screw includes a non-threaded portion adjacent an end of the lead screw.

40 (withdrawn). A device according to Claim 26, wherein the dispenser comprises:

- a clock spring operatively connected to the lead screw for rotating the lead screw;
- a gear radially extending from the lead screw; and

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a ratchet controlled by the local processor for movement between engaging the gear for preventing the clock spring from rotate the lead screw, and disengaging the gear for allowing the clock spring to rotate the lead screw.

41 (withdrawn). A device according to Claim 26, further comprising a sensor for determining the position of the plunger within the reservoir.

42 (withdrawn). A device according to Claim 41, wherein the lead screw includes a linear encoder and the sensor comprises a magnetic sensor mounted on the plunger.

43 (withdrawn). A device according to Claim 26, further comprising a release mechanism for allowing the plunger to be moved within the reservoir.

44 (withdrawn). A device according to Claim 25, further comprising a removable plug closing the exit port assembly.

45 (withdrawn). A device according to Claim 25, wherein the reservoir is unitarily formed with the housing.

46 (withdrawn). A device according to Claim 25, further comprising a shaft connected to the plunger, and the dispenser is adapted to linearly move the shaft.

47 (withdrawn). A device according to Claim 46 wherein the shaft is flexible.

48 (withdrawn). A system including a fluid delivery device according to Claim 25, and further comprising a remote control device separate from the fluid delivery device and including:

a remote processor;

user interface components connected to the remote processor for allowing a user to provide flow instructions to the remote processor, and

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a transmitter connected to the remote processor for transmitting the flow instructions to the receiver of the fluid delivery device.

49 (withdrawn). A device for delivering fluid to a patient, comprising:

- a) an exit port assembly adapted to connect to a transcutaneous patient access tool;
- b) a reservoir including an outlet connected to the exit port assembly;
- c) a plunger movably received in the reservoir for forcing fluid through the outlet to the exit port assembly upon moving within the reservoir;
- d) a dispenser for moving the plunger within the reservoir;
- e) a local processor connected to the dispenser and programmed to cause a flow of fluid to the exit port assembly based upon flow instructions, and further programmed to provide flow information;
- f) a wireless transmitter connected to the local processor for transmitting the flow information from the local processor to a separate, remote control device; and
- g) a housing containing the exit port assembly, the reservoir, the dispenser, the local processor, and the wireless transmitter;

wherein the housing is free of user output components for providing the flow information from the local processor to a user.

50 (withdrawn). A system including a fluid delivery device according to Claim 49 and further comprising a remote control device separate from the fluid delivery device and including:

- a remote processor;



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user output components connected to the remote processor for allowing a user to receive flow information, and

a receiver connected to the remote processor for receiving the flow information from the transmitter of the fluid delivery device.

51 (withdrawn). A system for delivering a fluid to a patient, comprising:

- a) a fluid delivery device for attachment to a skin surface of a patient and including,
  - an exit port assembly adapted to connect to a transcutaneous patient access tool,
  - a reservoir including an outlet connected to the exit port assembly,
  - a plunger movably received in the reservoir for forcing fluid through the outlet to the exit port assembly upon moving within the reservoir,
  - a dispenser for moving the plunger within the reservoir,
  - a local processor connected to the dispenser and programmed to cause a flow of fluid to the exit port assembly based at least in part on received flow instructions, and further programmed to provide flow information,
  - a wireless receiver connected to the local processor for receiving the flow instructions and delivering the flow instructions to the local processor,
  - a wireless transmitter connected to the local processor for transmitting the flow information from the local processor, and
  - a housing containing the exit port assembly, the dispenser, the local processor, the wireless receiver, and the wireless transmitter,

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wherein the housing is free of user input components for providing flow instructions to the local processor; and

b) a remote control device separate from the fluid delivery device and including,

user input components for receiving user inputs,

user output components for providing user outputs,

a remote processor connected to the user input components and programmed to provide the flow instructions based on the user inputs, and connected to the user output components to provide user outputs based upon the flow information,

a wireless transmitter connected to the remote processor for transmitting the flow instructions to the receiver of the fluid delivery device, and a wireless receiver connected to the remote processor for receiving the flow information from the transmitter of the fluid delivery device.